K132914

APR 0 3 2014

510(k) Summary

per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Holly Ramirez
Phone Number:	763-494-2113
Fax Number:	763-494-2222
Prepared:	September 16, 2013
Trade Name:	ACUITY™ Pro Lead Delivery System
Common Name:	Percutaneous Guide Catheter
Classification:	II
Product Code:	DQY 21 CFR 870.1250

Predicate Device:
ACUITY Break-Away™ Guide Catheters (K093969; March 05, 2010) and ACUITY Cut-Away™ Guide Catheters (K111252, June 02, 2011).

Device Description:
The ACUITY™ Pro Lead Delivery System is designed for venous use to aid in the selective placement of cardiac resynchronization therapy (CRT) implantable venous leads in the cardiac vasculature. The catheter shafts are comprised of a PTFE inner liner, a reinforcing layer of stainless steel braid, and an outer polymer jacket. The distal end has a radiopaque polymer tip, while the proximal end has a hub with flush luer fitting to allow flush, contrast injection and aspiration polymer .

The approximate working lengths of the catheters are 45-54cm for the 9F design and 60-69 cm for the 7F design.

The ACUITY Pro 9F is provided with the following accessories:

- Guidewire Introducer
- Guidewire Torquer
- Transvalve Introducer Tool (2)
- Venous Access Dilator
- ACUITY™ Universal Cutter

Intended Use:
The ACUITY™ Pro Lead Delivery System is intended to access the coronary venous system, and may be used alone (9F) or in a dual catheter delivery (9F with 7F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Substantial Equivalence:
The ACUITY™ Pro Lead Delivery System design, materials, manufacturing process and intended use are substantially equivalent to the ACUITY Break-Away™ Guide Catheter (K093969) and the ACUITY Cut-Away™ Guide Catheter (K111252).

Summary of Non-Clinical Testing:
Design verification and validation testing, including mechanical bench testing, and animal testing, was performed to verify that the performance and usability of the ACUITY™ Pro Lead Delivery System remains substantially equivalent to both predicate devices. Biocompatibility, sterility, and packaging testing were also performed to verify the overall safety and efficacy of the device.

Specifically the following design verification and validation testing was performed:

- Dimensional Verification
- Tensile
- Pushability and Shaft Stiffness
- Shaft Cutting
- Kink Resistance
- Curve Shape
- Radiopacity
- Curve Shape
- Tip Deflection
- Torque Strength
- Hub Leak
- Hub Separation
- Hub Cutting /Catheter Removal
- Compatibility With Accessories And Adjunctive Devices
- Lead Passage
- Product Marking And Identification
- Product Integrity
- Ease Of Removal Of Device And Accessories From Packaging
- Particulates
- Microbiology Endotoxin
- EO Residuals
- Biocompatibility Testing
  - Cytotoxicity
  - Sensitization
  - Irritation Or Intracutaneous Reactivity
  - Systemic Toxicity (Acute)
  - Hemocompatibility
  - Latex
  - USP Physicochemical

Summary of Clinical Testing:
Clinical Evaluation was not required for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

Boston Scientific Corporation
% Holly Ramirez
Sr. Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K132914
Trade/Device Name: ACUITY™ Pro Lead Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 27, 2014
Received: March 28, 2014

Dear Holly Ramirez,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132914

Device Name: ACUITY Pro Lead Delivery System

Indications for Use:

The ACUITY™ Pro Lead Delivery System is intended to access the coronary venous system, and may be used alone (9F) or in a dual catheter delivery (9F with 7F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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